PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2005/000135	04.02.2005	05.02.2004

International Patent Classification (IPC) or both national classification and IPC
A61N1/36, A61B5/0488

Applicant
REABILITY INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2005/000135

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 36-46

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 36-46

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	8-13,15,20-22,34-35
	No:	Claims	1-7,14,16-19,23-33
Inventive step (IS)	Yes:	Claims	20-22
	No:	Claims	1-19,23-35
Industrial applicability (IA)	Yes:	Claims	1-35
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Re Item V.

Reference is made to the following documents:

D1 : WO 02/092164 A

D2 : US 4 582 049 A

D3 : GRAUPE D: "EMG PATTERN ANALYSIS FOR PATIENT-RESPONSIVE CONTROL OF FES IN PARAPLEGICS FOR WALKER-SUPPORTED WALKING" IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, IEEE INC. NEW YORK, US, vol. 36, no. 7, 1 July 1989 (1989-07-01), pages 711-719

D4 : WO 02/13673 A

1. The application does not meet the requirements of Article 6 PCT, because claims 1, 7 and 31 are not clear. The reasons are as follows:

1.1 Claim 1:
The limitations intended by the expression "a controller which ... expects a motion of the paretic body part" is not clear. Furthermore the wording "said NMES stimulation is not sufficient, on its own, to move said paretic body part said expected motion" is not well-defined (no technical feature; furthermore patient-dependent and even dependent on e.g. fatigue), thereby rendering the definition of the subject-matter of claim 1 unclear.

The above features have thus not been considered when assessing claim 1 with regard to novelty and inventive step.

1.2 Similarly, the definition of the stimulation amplitude in dependent claim 7 is not clear (no technical feature; patient-dependent).

1.3 Claim 31:

The expression "class of patients" in claim 31 is not clear. Furthermore, in analogy to point 1.1 above, the expression "wherein the amplitude of stimulation is not sufficient by itself to cause contraction of said muscle, but the amplitude of stimulation is sufficient to cause contraction of said muscle when a patient in said class attempts to move the body part at the same time" leads to a lack of clarity and has not been considered when assessing claim 31 with regard to novelty and inventive step.

2. Taking into account the above-mentioned lack of clarity, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

Document D1 discloses (the references in parentheses applying to this document) an apparatus for rehabilitating a patient who has a paretic body part, the apparatus comprising:

a) at least one electromyography (EMG) sensor adapted to being applied to a voluntary muscle of a healthy body part of the same type as the paretic body part, which at least one sensor produces at least one EMG signal (last para. on p. 19);

b) a neuromuscular electrical stimulation (NMES) device (33) adapted for stimulating at least one voluntary muscle of the paretic body part (cf. also para. bridging p. 17 and p. 18);

c) a controller which controls the NMES device, making the amplitude of stimulation of the paretic body part at least partly dependent on the EMG signal from the healthy body part (last two paras. on p. 19).

3.1 Dependent claims 2-6, 8-16, 18, 19 and 23-30 do not appear to add anything new or inventive with regard to D1, see in particular:

Claims 2-5, 18, 19: last two paras. on p. 19

Claim 6: implicit, since the controller in D1 is configured to decrease the amplitude of one muscle of an antagonistic pair of muscles when the EMG signal of this muscle in the healthy body part decreases, which is likely to occur simultaneously with an increase of the EMG signal of the other muscle of the antagonistic pair in the movement of the

	healthy body part
Claims 8-13:	obvious design possibility
Claims 14, 16:	cf. fig. 1
Claim 15:	it would be obvious to apply the principles disclosed in D1 to an arm instead of a leg
Claims 23-26:	p. 14 para. 8 - p. 15 para. 3 in combination with last para. on p. 19, regarding the position sensing device cf. also last para. on p. 18
Claims 27-30:	2nd para. on p. 15

3.2 The subject-matter of claim 17 is known from document D2, which discloses an apparatus comprising:
an EMG sensor adapted to being applied to a voluntary muscle of a healthy body part of the same type as the paretic body part, which at least one sensor produces at least one EMG signal (cf. col. 5 l. 38-40 and col. 2 l. 51-61);
a NMES device adapted for stimulating at least one voluntary muscle of a paretic body part (col. 5 l. 40-44); and
a controller which controls the NMES device, making the amplitude of stimulation of the paretic body part at least partly dependent on the EMG signal from the healthy body part (col. 5 l. 33-50). The healthy body part and the paretic body part belong to the same person.

The subject-matter of claim 17 is also known from D3 (cf. p. 711, left hand col. last four lines, and first para. of right hand col., and fig. 3).

4. The combination of the features of dependent claims 20-22 is neither known from, nor rendered obvious by, the available prior art, cf. also the respective advantages on p. 8 l. 28-29, p. 9 l. 15-21 and p. 16 l. 32 - p. 17 l. 4 of the present application.

5. Taking into account the observations under point 1.3 above, the subject-matter of claim 31 is not new in the sense of Article 33(2) PCT.

D4 discloses an apparatus (10) adapted for rehabilitating a patient who has a paretic body part, the apparatus comprising a NMES device (104) adapted to stimulate at least one voluntary muscle in the paretic body, wherein the stimulation is triggered

when the EMG signal of a patient that voluntarily tries to activate the paretic body part reaches a threshold value (p. 10 l. 25-32) and wherein the movement established by the stimulation is compatible to the patient's effort (p. 12 l. 25 - p. 13 l. 2).

6. Dependent claims 32-35 do not appear to add anything new or inventive with regard to D4, see in particular:

Claim 32: p. 10 l. 26-28, p. 11 l. 21-28

Claim 33: p. 12 l. 27 - p. 13 l. 2 (it is noted that already the triggering implies that the amplitude of stimulation depends on the EMG signal, since a non-vanishing amplitude is only chosen if the EMG signal reaches the threshold)

Claim 34-35: obvious design possibility.